# BASIC CARE CHILDRENS IBUPROFEN- ibuprofen tablet, chewable L. Perrigo Company

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### Amazon Children's Ibuprofen Drug Facts

# Active ingredient (in each chewable tablet)

Ibuprofen 100 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

### **Purposes**

Pain reliever/fever reducer

#### Uses

temporarily:

- reduces fever
- relieves minor aches and pains due to the common cold, flu, sore throat, headaches and toothaches

# **Warnings**

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if your child:

- has had stomach ulcers or bleeding problems
- takes a blood thinning (anticoagulant) or steroid drug
- takes other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- takes more or for a longer time than directed

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Sore throat warning:** Severe or persistent sore throat or sore throat accompanied by high fever,

headache, nausea, and vomiting may be serious. Consult doctor promptly. Do not use more than 2 days or administer to children under 3 years of age unless directed by doctor.

#### Do not use

- if the child has ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

#### Ask a doctor before use if

- stomach bleeding warning applies to your child
- child has a history of stomach problems, such as heartburn
- child has problems or serious side effects from taking pain relievers or fever reducers
- child has not been drinking fluids
- child has lost a lot of fluid due to vomiting or diarrhea
- child has high blood pressure, heart disease, liver cirrhosis, kidney disease, or had a stroke
- child has asthma
- child is taking a diuretic

# Ask a doctor or pharmacist before use if the child is

- under a doctor's care for any serious condition
- taking any other drug

#### When using this product

- mouth or throat burning may occur; give with food or water
- take with food or milk if stomach upset occurs

#### Stop use and ask a doctor if

- child experiences any of the following signs of stomach bleeding:
- feels faint
- vomits blood
- has bloody or black stools
- has stomach pain that does not get better
- child has symptoms of heart problems or stroke:
- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling
- the child does not get any relief within first day (24 hours) of treatment
- fever or pain gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

# Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

#### **Directions**

- chew or crush tablets completely before swallowing
- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find right dose on chart below. If possible, use weight to dose; otherwise use age.
- if needed, repeat dose every **6-8 hours**
- · do not use more than 4 times a day

| Dosing Chart |          |              |  |
|--------------|----------|--------------|--|
| Weight (lb)  | Age (yr) | Tablets      |  |
| under 24     | under 2  | ask a doctor |  |
| 24-35        | 2-3      | 1            |  |
| 36-47        | 4-5      | 1 ½          |  |
| 48-59        | 6-8      | 2            |  |
| 60-71        | 9-10     | 2 ½          |  |
| 72-95        | 11       | 3            |  |

#### Other information

- phenylketonurics: contains phenylalanine 6 mg per tablet
- store between 20-25°C (68-77°F)
- do not use if printed seal under cap is broken or missing

# **Inactive ingredients**

acesulfame potassium, ammonium glycyrrhizin, aspartame, carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, mannitol, natural and artificial flavors, silicon dioxide, sodium lauryl sulfate, soybean oil, succinic acid

#### Questions or comments?

1-800-719-9260

# Package/Label Principal Display Panel

Compare to Children's Motrin® active ingredient

for ages 2 to 11

children's ibuprofen Chewable Tablets, 100 mg

Pain Reliever/Fever Reducer (NSAID)

Lasts up to 8 hours | Orange Flavor

Chewables

Chew or crush tablets completely before swallowing

Dye-Free

actual size

24 ORANGE-FLAVORED TABLETS







KEEP CARTON FOR REFERENCE

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| 72-95                        | 11            | 3           |

Other inder mation

If the plan yketonurics contains phenyldamine 6 mg per tath

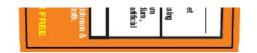
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Inactive ingredients accustene potass turn, ammoningly py frisin, as partame, car naubawar, coscarned lose contrypomeltose, magnes iums teateb, marrich, natural and itavors, silbondoxide, scalium huryl suffate, so phen oil, succinit acid Questions or comments? 1-80 0-719-9260

Drug

facts(continued)



# **BASIC CARE CHILDRENS IBUPROFEN**

ibuprofen tablet, chewable

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-7619

Route of Administration ORAL

#### **Active Ingredient/Active Moiety**

| <b>8</b>  |                   |          |
|---|-------------------|----------|
| Ingredient Name   | Basis of Strength | Strength |
| IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM) | IBUPROFEN         | 100 mg   |

| Inactive Ingredients                      |          |  |
|---|----------|--|
| Ingredient Name                           | Strength |  |
| ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)   |          |  |
| ASPARTAME (UNII: Z0H242BBR1)              |          |  |
| CARNAUBA WAX (UNII: R12CBM0 EIZ)          |          |  |
| CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48) |          |  |
| HYPROMELLOSES (UNII: 3NXW29V3WO)          |          |  |
| MAGNESIUM STEARATE (UNII: 70097M6I30)     |          |  |
| MANNITOL (UNII: 3OWL53L36A)               |          |  |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)      |          |  |
| SODIUM LAURYL SULFATE (UNII: 368 GB5141J) |          |  |
| SO YBEAN O IL (UNII: 241ATL177A)          |          |  |
| SUCCINIC ACID (UNII: AB6MNQ6J6L)          |          |  |

| Product Characteristics |                   |              |          |
|-------------------------|-------------------|--------------|----------|
| Color                   | WHITE (off white) | Score        | 2 pieces |
| Shape                   | ROUND             | Size         | 13mm     |
| Flavor                  | ORANGE            | Imprint Code | L7W6     |
| Contains                |                   |              |          |

| Packaging          |   |                             |                           |
|--------------------|---|-----------------------------|---------------------------|
| # Item Code        | Package Description                               | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 NDC:0113-7619-62 | 1 in 1 CARTON                                     | 02/19/2019                  |                           |
| 1                  | 24 in 1 BOTTLE; Type 0: Not a Combination Product |                             |                           |

| <b>Marketing Infor</b> | mation                                   |                      |                    |
|------------------------|--|----------------------|--------------------|
| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |

| ANDA | ANDA076359 | 0 2/19/20 19 |
|------|------------|--------------|
|      |            |              |

# Labeler - L. Perrigo Company (006013346)

Revised: 2/2019 L. Perrigo Company